

ISEP 28 2001

DOT-E 11854 (FOURTH Revision)

EXPIRATION DATE: May 31, 2003

(FOR RENEWAL, SEE 49 CFR 107.109)

- 1. <u>GRANTEE</u>: Plastic Omnium Zarn, Inc. Reidsville, North Carolina
- 2. <u>PURPOSE AND LIMITATIONS</u>: This exemption authorizes the manufacture, marking and sale of high density polyethylene injection molded bins as outer packagings for the transportation in commerce of regulated medical waste in dual packagings. This exemption provides no relief from any regulation other than as specifically stated herein.
- 3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
- 4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 172.101 Column (8.c) and § 173.197.
- 5. <u>BASIS</u>: This exemption is based on the application of Plastic Omnium Zarn, Inc. dated June 29, 2001, submitted in accordance with § 107.109 and supplemental information dated September 27, 2001.
- 6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous materials description proper shipping name	Hazard Class/ Division	Identi- fication Number	Packing Group
Regulated medical waste	6.2	UN3291	II

7. PACKAGING(S) and SAFETY CONTROL MEASURES:

a. <u>PACKAGING</u> - The packaging authorized is a dual packaging which consists of an outer packaging and an inner packaging as follows:

- The outer packaging is a high density polyethylene injection molded bin not greater than 800 L (211 gallons) in size, called 4000MW containers. Each bin is a solid, one-piece body of smooth wall, injected mold construction, with hinged and gasketed lid.
- 2. The outer packaging may be reused provided it has an interior surface that is smooth, non-porous and free of cracks or other defects that could obstruct decontamination operations. The exterior surface must be non-porous and easy to decontaminate.
- 3. All regulated medical waste must be contained in inner packagings that are securely closed and leak resistant.
- 4. Plastic film bags may not exceed a volume of 150 L (40 gallons) and must have a film thickness of no less than 3 mils.
- 5. Puncture-resistant sharps containers may not be greater than 38 L (10 gallons) in volume.
- 6. Inner packagings for liquids may not exceed 19 L (5 gallons) capacity and must meet the non-bulk packaging standards for Packing Group I for liquids.
- b. <u>TESTING</u> The outer packaging must be capable of meeting the requirements of § 178.603 (drop test) and § 178.606 (stacking test), as specified for the Packing Group II performance level.

c. OPERATIONAL CONTROLS -

- 1. Waste materials containing small amounts of liquid may be packaged as solids provided the inner container has sufficient absorbent materials to absorb and retain all liquid during transportation.
- 2. Prior to transporting a package containing regulated medical waste, the carrier must perform an external visual inspection of each outer packaging to determine that it is properly closed, locked and free of leakage.
- 3. Outer packagings are authorized for the transportation of regulated medical waste only if such packagings are dedicated exclusively to the transportation of waste materials.

- Prior to being reused, any outer packaging must be decontaminated.
- The owners and users of the container authorized by this exemption are responsible for informing the persons responsible for placing waste materials in the inner packagings of the limitation on liquids in packagings for solids.

8. SPECIAL PROVISIONS:

- a. In accordance with the provisions of Paragraph (b) of § 173.22a, persons may use the packaging authorized by this exemption for the transportation of the hazardous materials specified in paragraph 6, only in conformance with the terms of this exemption.
- A person who is not a holder of this exemption, but receives a package covered by this exemption, may reoffer it for transportation provided no modifications or changes are made to the package and it is offered for transportation in conformance with this exemption and the HMR.
- A current copy of this exemption must be maintained at each facility where the package is offered or reoffered for transportation.
- Each packaging manufactured under the authority of this exemption must be either (1) marked with the name of the manufacturer and location (city and state) of the facility at which it is manufactured or (2) marked with a registration symbol designated by the Office of Hazardous Materials Exemptions and Approvals for a specific manufacturing facility.
- A current copy of this exemption must be maintained at each facility where the package is manufactured under this exemption. It must be made available to a DOT representative upon request.
- MARKING The outside of each outer packaging must be plainly and durably marked "DOT-E 11854".
- MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle. 9.

- 10. MODAL REQUIREMENTS: A current copy of this exemption must be carried aboard each motor vehicle used to transport packages covered by this exemption.
- 11. <u>COMPLIANCE</u>: Failure by a person to comply with any of the following may result in suspension or revocation of this exemption and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 <u>et seq</u>:
 - o All terms and conditions prescribed in this exemption and the Hazardous Materials Regulations, Parts 171-180.
 - o Registration required by \$ 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8 who performs a function subject to this exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704

No person may use or apply this exemption, including display of its number, when the exemption has expired or is otherwise no longer in effect.

12. REPORTING REQUIREMENTS: The carrier is required to report any incident involving loss of packaging contents or packaging failure to the Associate Administrator for Hazardous Materials Safety (AAHMS) as soon as practicable. (Sections 171.15 and 171.16 apply to any activity undertaken under the authority of this exemption.) In addition, the holder(s) of this exemption must also inform the AAHMS, in writing, as soon as practicable of any incidents involving the package and shipments made under this exemption.

Issued in Washington, D.C.

Robert A. McGuire

Associate Administrator

for Hazardous Materials Safety

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DATE

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, Department of Transportation, Washington, D.C. 20590. Attention: DHM-31.

The original of this exemption is on file at the above office. Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

Copies of exemptions may be obtained from the AAHMS, U.S. Department of Transportation, 400 7th Street, SW, Washington, DC. 20590-0001, Attention: Records Center, 202-366-5046.

PO: sln